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Increasing the Efficiency of Laboratory Performance by Using the Onboard Dilution Algorithm of the Elecsys Hepatitis B Surface Antigen II Quantitative Assay

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Background: The Elecsys hepatitis B surface antigen (HBsAg) II quantitative assay is a newly introduced electrochemiluminescence immunoassay incorporating an initial 1:400 onboard dilution and a simple algorithm to determine HBsAg levels in serum. We evaluated the performance of the Elecsys HBsAg II assay and determined the impact of its initial onboard dilution on laboratory efficiency.
Methods: HBsAg levels were determined using both Roche Elecsys and Abbott Architect HBsAg assays. Linearity and precision of the Elecsys HBsAg II assay and its correlation with the Architect HBsAg assay were evaluated. In particular, precision was verified at Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital in Seoul, using the same pooled serum controls. The efficiency of the dilution algorithm for both methods was verified using data from 1,848 clinical samples.
Results: The Elecsys HBsAg II assay showed a good linearity from 0.1 to 48,000.0 IU/mL and a good correlation (r=0.9998) between expected and measured values. Precision analyses performed at Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital showed excellent performance with coefficients of variation between 1.28% and 6.82%. The values of the Elecsys HBsAg II and Architect HBsAg assays were well correlated (n=506, r=0.987, P <0.001) and also reliably determined in hepatitis C virus- and hepatitis B virus-co-infected patient sera (n=27). In terms of efficiency, 64.0% of samples provided a final HBsAg result on the first run without the need for further dilution, when using the 1:400 onboard predilution protocol of the Elecsys HBsAg II assay.
Conclusions: Given the excellent precision and correlation with the Architect assay, the Elecsys HBsAg II assay showed a potential advantage for laboratory efficiency by significantly reducing the need for retesting samples with high HBsAg levels.
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Key Words : Hepatitis B surface antigens, Elecsys HBsAg II, Architect HBsAg, Hepatitis B virus, Chronic hepatitis B

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INTRODUCTION

The quantification of hepatitis B surface antigen (HBsAg) and hepatitis B virus (HBV) DNA levels is expected to play an important role in predicting and evaluating antiviral therapy responses in patients with chronic HBV hepatitis [1,2]. Recent studies suggested that the slow kinetics of covalently closed circular DNA (cccDNA) under powerful antiretroviral treatment is a main cause of viral rebound after interruption of long-term therapy [3,4]. Serum HBsAg is a marker that can predict the presence of cccDNA in a simple way without invasive liver biopsy, because serum HBsAg quantification in patients with chronic hepatitis B permits a good correlation with hepatocyte nuclear cccDNA levels. In patients with low viral loads, hepatocellular carcinoma (HCC) risk is determined by levels of HBsAg, alanine aminotransferase, and age, but not HBV DNA [5].

Currently, two fully automated HBsAg assays are commercially available: the Architect HBsAg assay (Abbott Diagnostics, Abbott Park, IL, USA) and the Elecsys HBsAg II (Roche Diagnostics, Indianapolis, IN, USA). The earlier developed Architect HBsAg assay is predominantly optimised for low-level detection and does not fully meet the requirements of follow-up under a laboratory perspective. Evaluation studies with clinical samples revealed varying values of HBsAg depending on infection phases. The immune-tolerant phase presented the highest median HBsAg levels, ranging from 4.5 to 5.0 log10 IU/mL, and even an extremely high level of up to 6.0 log10 IU/mL has been reported [6-9]. The Elecsys HBsAg II is a new quantitative electrochemiluminescence immunoassay, incorporating an initial 1:400 onboard dilution and a simple algorithm to determine HBsAg levels in serum. This may allow for the majority of samples from actively HBV infected patients to be measured without further manual dilution, thereby facilitating laboratory automation.

Here, we aimed to evaluate (1) the precision of HBsAg quantification results in clinical laboratories of Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital in Seoul, (2) the correlation between the Roche Elecsys HBsAg II quantitative assay and the Abbott Architect assay as applied to patients with HBV infection, and (3) the efficiency of the onboard dilution algorithm of the Roche Elecsys HBsAg II assay under the perspective of laboratory workload at Samsung Medical Center.

MATERIALS AND METHODS

1. Subjects and Controls

This evaluation study was conducted from August to September 2011 at Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital in Seoul, Korea. Control sera used for the performance evaluation were produced at Samsung Medical Center and distributed to Severance Hospital, Seoul St. Mary's Hospital under identical conditions. For linearity assessment, pooled sera containing 43,654 IU/mL were diluted with normal sera. Pooled sera with low, medium and high levels of HBsAg, predetermined by the Abbott Architect HBsAg reagent kit, were used as control samples for precision analyses. From 31 August to 26 September 2011, sera used for the correlation analysis of the two assays were randomly selected from the samples requesting HBsAg analysis at the Division of Hepatology of Samsung Medical Center.

The 1,848 results of HBsAg quantification by the Abbott Architect assay were archived retrospectively, in order to assess the efficiency of the onboard dilution algorithm of the Roche Elecsys HBsAg II assay. Those results were generated from the samples mainly requested by the Division of Hepatology of Samsung Medical Center between 1 August and 30 September 2011. Clinical samples enrolled in correlation assessment were from patients with chronic hepatitis B, liver cirrhosis, and HCC. The 386 patients consisted of 253 males (66%) and 133 females (34%). Mean age was 54 years with a standard deviation of 12 years. HBV infection phase and disease stage data were only available from Samsung Medical Center. This study was carried out with the approval of the institutional review board of Samsung Medical Center (2011-06-088).

2. Performance Evaluation Protocol

Linearity and precision of the Elecsys HBsAg II assays were verified using the pooled control sera according to the Clinical and Laboratory Standards Institute (CLSI) guidelines. For precision, repeatability and total imprecision evaluation (according to EP05-A2), the center A: Samsung Medical Center, center B: Severance Hospital, center C: Seoul St. Mary's Hospital used the same study protocol and control materials, which were distributed to each laboratory as multiple frozen aliquots so that they would be thawed only once before analysis. The linearity of dilution recovery (according to EP06-A), using control materials, and the correlation of the Elecsys HBsAg II assay with the Abbott Architect HBsAg assay using clinical samples (according to CLSI EP09-A2) were evaluated at Samsung Medical Center. The efficiency of the onboard dilution algorithm was verified by simulation of the proportion of samples at the final HBsAg levels that were generated without retesting in the Roche Elecsys HBsAg II assay, using retrospective test results of the Abbott Architect HBsAg assay.

3. Quantification of Hepatitis B Surface Antigen

HBsAg levels were determined using the quantitative Elecsys HBsAg II and Abbott Architect HBsAg assays. The Elecsys HBsAg II assay is an in vitro diagnostic electrochemiluminescence immunoassay for the quantification of HBsAg in human serum and plasma using the sandwich principle on the Modular Analytics E170, cobas e 601 and cobas e 602 analysers. An initial 1:400 onboard dilution is mandatory for every sample, as described in Fig. 1. If the result for a 400-fold diluted sample falls within 20 to 52,000 IU/mL, no further dilution is necessary and an endpoint result is achieved. If a result falls below the above-mentioned range, the sample has to be re-run undiluted and should return 0.05 to 130 IU/mL. If a result returns >52,000 IU/mL for a 400-fold diluted sample, further manual dilution steps are recommended until results fall into the clinically relevant ranges. To evaluate this dilution procedure, a series of manual dilutions were performed for each sample.

The Abbott Architect HBsAg assay is a two-step immunoassay, using chemiluminescent microparticle immunoassay technology for the quantitative determination of HBsAg in human serum and plasma. A specimen with a concentration greater than or equal to 0.05 IU/mL is considered reactive for HBsAg. If the HBsAg value exceeds 250 IU/mL, repeated measurement of the HBsAg level, using 1:500 manually or automatically diluted specimens, is recommended. The dilution algorithm of the Roche Elecsys HBsAg II assay is described in Fig. 1, along with that of the Abbott Architect HBsAg assay.

4. Data Analysis

The respective dilution factor was used to calculate the final HBsAg level from the obtained measurement values of samples. In order to guarantee that our results would not be biased by outliers from undetectable levels, all values of <0.05 IU/mL were imputed as zero (n=78).

For precision analysis, the mean, SD, and CV were given at each HBsAg level. Linear regression and Pearson correlation analysis were used to establish the relationship between the two methods. Bland-Altman plots were generated to determine the limits of agreement for the comparison between the two sets of data, using the Elecsys assay as the dependent variable and the Architect

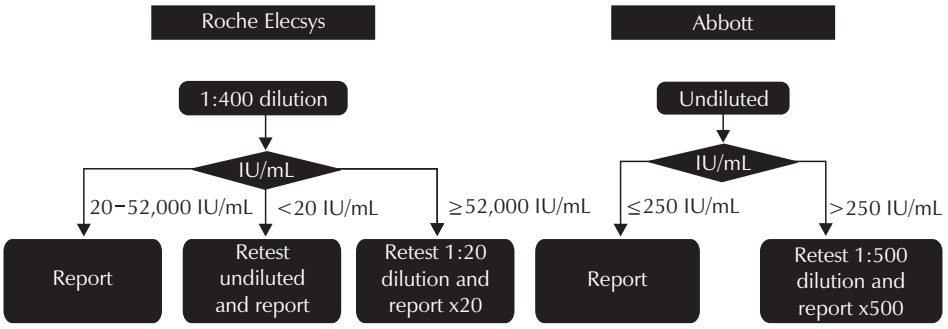

Fig. 1. Onboard dilution algorithm of Roche Elecsys, in comparison with Abbott Architect.

assay as the independent variable.

RESULTS

1. Linearity and Precision Assessment of Roche Elecsys Hepatitis B Surface Antigen II Quantitative Assay

The Elecsys HBsAg II assay showed linearity from 0.1 to 48,000.0 IU/mL and a good correlation (r=0.9998, r^2=0.9997) between measured and expected values (Fig. 2). Precision analyses performed at the Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital with control samples ranging from 65.11 to 19,569.26 IU/mL showed excellent performance with coefficients of variation between 1.28% and 6.82% (Table 1).

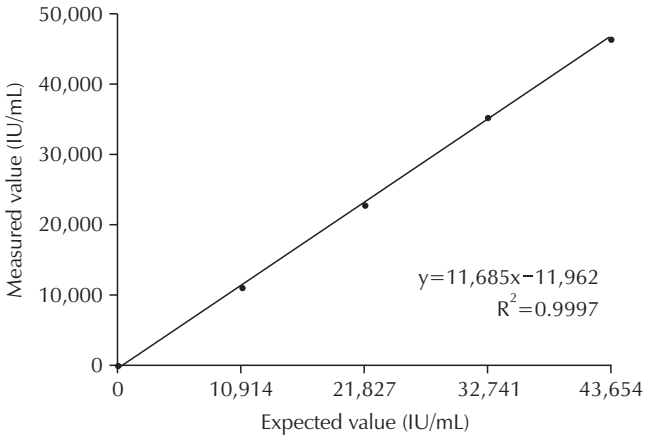

Fig. 2. Linearity by dilutional recovery.

2. Correlation between Results of the Roche Elecsys Hepatitis B Surface Antigen II Quantitative Assay and the Abbott Architect Hepatitis B Surface Antigen Assay

A total of 386 serum samples from 386 patients were included in the analysis. The agreement of positive and negative results between the two assays was 99.5% (384/386); two negative results of the Abbott Architect were positive in the Roche Elecsys assay. As shown in Fig. 3, there was an excellent correlation between the HBsAg values determined by the two assays (correlation coefficient r=0.987, P<0.001), and differences between their results were expressed by a Bland-Altman plot (mean, 70.8; 95% confidence interval, −1,158.8 to 1,300.4). In addition, HBsAg levels were reliably determined in HCV- and HBV-co-infected patient sera (n=27).

3. Assessment of the Efficiency of the Mandatory Onboard Dilution Algorithm

For the simulation of the workload of the Roche Elecsys HBsAg II assay with mandatory onboard dilution of specimens, 1,848 retrospective test results of the Abbott Architect HBsAg assay, acquired from patients mainly

Table 1. Precision of hepatitis B surface antigen measurement in a multi-center setting

	Instrument	Material	Mean	Imprecision SD (CV%)			
				Between-day	Between-run	Within-run	Total
Center A	Modular analytics E170						
		Low	71.19	2.63 (3.69)	2.98 (4.19)	1.75 (2.45)	3.26 (4.58)
		Medium	1,665.39	58.44 (3.51)	65.90 (3.96)	32.18 (1.93)	70.5 (4.23)
		High	18,836.72	794.60 (4.22)	870.78 (4.62)	421.63 (2.24)	931.4 (4.94)
Center B	Modular analytics E170						
		Low	65.11	1.34 (2.06)	1.81 (2.78)	1.23 (1.89)	2.02 (3.10)
		Medium	1,568.43	26.02 (1.66)	36.53 (2.33)	38.61 (2.46)	45.82 (2.92)
		High	18,999.43	933.92 (4.90)	1,247.31 (6.56)	465.44 (2.44)	1,300.38 (6.82)
Center C	Cobas 6000						
		Low	73.37	0.94 (1.28)	2.17 (2.96)	1.20 (1.63)	2.35 (3.19)
		Medium	1,671.75	34.59 (2.06)	50.50 (3.02)	30.92 (1.84)	55.60 (3.31)
		High	19,569.26	417.95 (2.13)	626.94 (3.20)	363.95 (1.85)	687.47 (3.50)

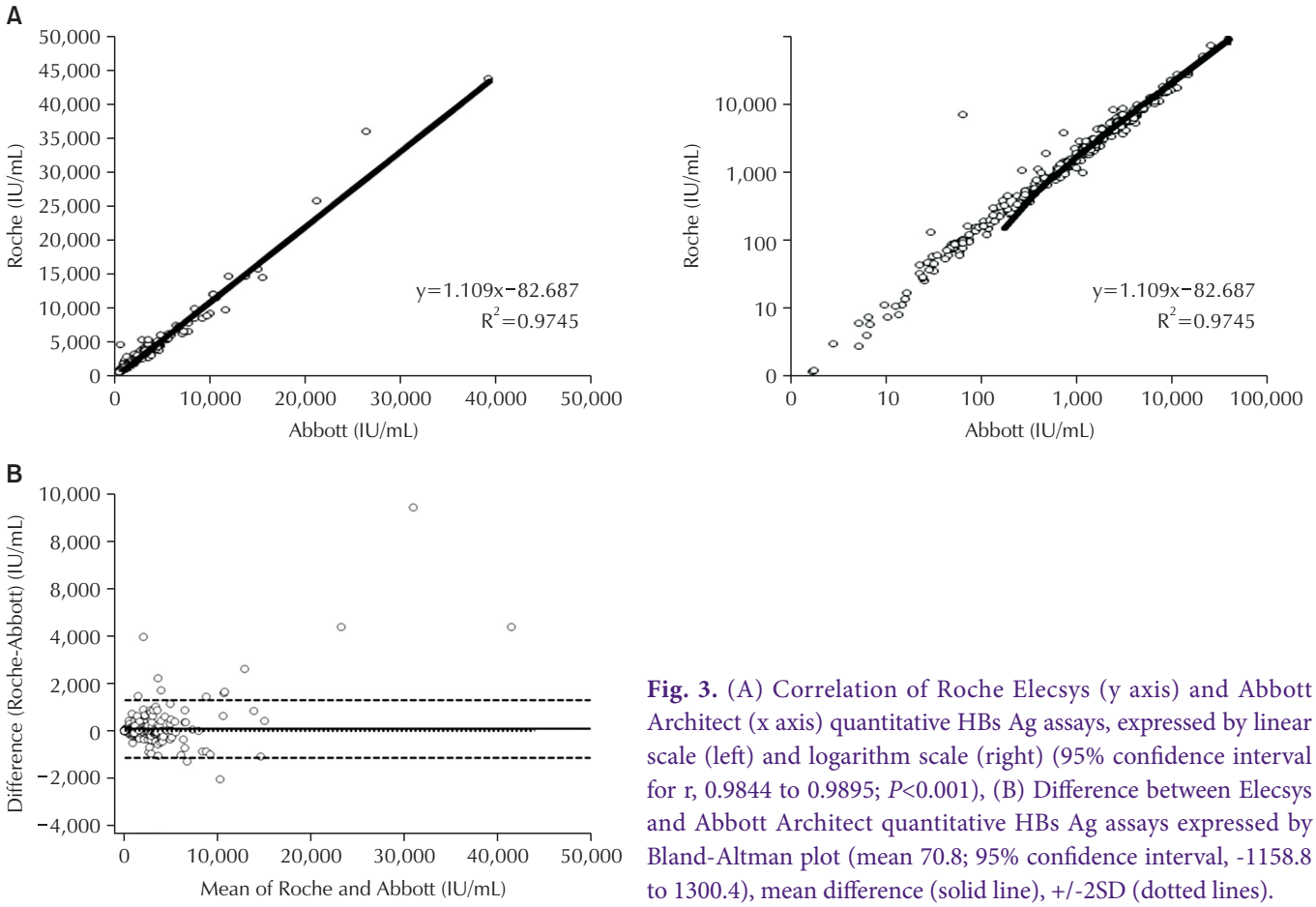

Fig. 3. (A) Correlation of Roche Elecsys (y axis) and Abbott Architect (x axis) quantitative HBs Ag assays, expressed by linear scale (left) and logarithm scale (right) (95% confidence interval for r, 0.9844 to 0.9895; *P*<0.001), (B) Difference between Elecsys and Abbott Architect quantitative HBs Ag assays expressed by Bland-Altman plot (mean 70.8; 95% confidence interval, -1158.8 to 1300.4), mean difference (solid line), +/-2SD (dotted lines).

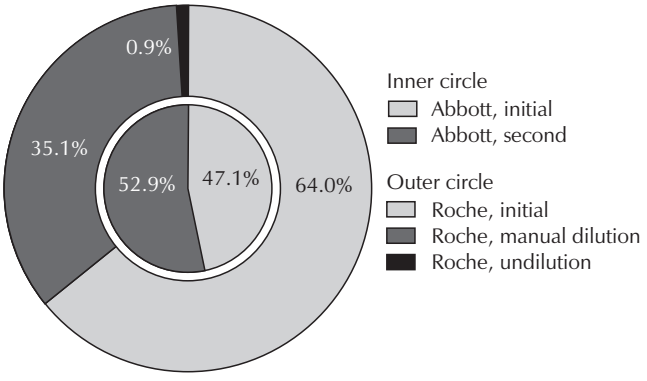

Fig. 4. Impact of dilution algorithm affecting laboratory efficiency.

referred by the Division of Hepatology, were included. By using 1:400 pre-dilution of samples, final HBsAg levels could be determined in 64.0% of the samples (1,183/1,848) during the first run. In other words, 36.0% of clinical samples required further dilution or no dilution in the Roche Elecsys HBsAg II quantitative assay, while 52.9% of samples had to be analysed repeatedly to determine final HBsAg levels in the Abbott Architect HBsAg assay, using no initial pre-dilution protocol (Fig. 4).

DISCUSSION

HBsAg is the oldest but clearest marker of both acute and chronic HBV infection [10]. Traditionally, the clinical use of HBsAg had been limited to qualitative assays. While quantification of HBsAg was introduced twenty years ago, it reached clinical significance only recently, when newly developed quantitation reagents were adopted in automated analysers.

Quantification of serum HBsAg is an emerging biomarker for prognosis and treatment response in chronic

hepatitis B [11] and can predict cccDNA in a simple way without invasive liver biopsy. cccDNA resides in an infected hepatocyte nucleus as a stable, resistant, and enduring non-integrated minichromosome, acting as a template for the transcription of viral genes and being responsible for viral persistence. Therefore, the challenge of antiviral therapy for chronic hepatitis B is to clear the liver of cccDNA. HBsAg levels should theoretically reflect the amount of total cccDNA in the liver as well as its transcriptional activity. A positive correlation between HBsAg levels, serum HBV DNA, and liver cccDNA has been noted in most studies of HBsAg-positive patients [12,13].

As values of HBsAg quantification can range from 0 to 6.0 log10 IU/mL in clinical samples [6-9], any quantitative assay is required to be reproducible between 0 and extremely high levels. As the earlier developed Abbott Architect HBsAg assay is predominantly optimised for low-level detection, not fully meeting the requirements of follow-up under a laboratory perspective, specimens with an HBsAg value exceeding 250 IU/mL are flagged with the code '>250.00 IU/mL' and need to be diluted up to 1:500, using a manual dilution procedure. Before the recent arrival of an Architect assay that includes automatic onboard dilution for designated specimens, the manual dilution procedure was the main weakness of this assay.

Several recent studies indicated that the newly introduced Roche Elecsys HBsAg II quantitative assay showed favourable performance and good correlation with the established Abbott Architect HBsAg assay [8,14-19]. Here, we also revealed that the Roche Elecsys HBsAg II quantitative assay, as used at Samsung Medical Center, Severance Hospital, Seoul St. Mary's Hospital in Korea, showed good performance in linearity and precision.

Our study confirms previous results using a research protocol for the quantification of HBsAg based on the quantitative Elecsys HBsAg II assay that also correlated well with the Abbott Architect assay. As its clinical use continues to be defined and elaborated, it is likely that HBsAg quantification will become an established part of patient management.

In addition, the treatment of co-infections by HBV and other viruses such as HIV and HCV has clinical implications in association with the immune status [20-22]. A previous study showed that the Elecsys assay is fully capable of quantifying serum HBsAg levels in HIV-HBV-co-infected patients, with very high correlation and precision compared to the Architect assay [8]. In that study, the authors described no substantial difference between methods in HIV-HBV-co-infected patients with HCV-positive and HCV-negative serology. The present study also shows that HBsAg levels were reliably determined in HCV-HBV-co-infected patients.

As described above, HBsAg levels can be as high as 4.5 to 5.0 log10 IU/mL in clinical samples [6-9]. The onboard dilution algorithm is one of the key benefits of the Elecsys HBsAg II quantitative assay, minimising the need for retesting samples with high amounts of HBsAg that exceed the actual measurement range of the test reagent. Our data showed that 1,183 of 1,848 samples (64.0%) tested using the 1:400 onboard dilution algorithm returned a final HBsAg result on the first run without the need of further dilution. On the other hand, the Architect HBsAg assay needed further dilution in 52.9% of clinical samples after initial undiluted measurement.

These results were mainly derived from both inpatients and outpatients visiting the Division of Hepatology. The efficiency of the clinical laboratory was increased by using the onboard dilution algorithm of the Elecsys HBsAg II assay, as the proportion of samples from HBV infected patients was relatively large. Considering the necessity of additional runs of the Roche Elecsys HBsAg II assay with undiluted sera of negative or low level samples (<20 IU/mL), it would be prudent to apply this assay selectively for HBV-infected patients, found with a qualitative HBsAg assay, in order to magnify the efficiency of the onboard dilution system. Otherwise, testing efficiency may deteriorate. Above all, to make the best use of the clinical significance of HBsAg levels, quantitative assays may be preferentially used in hepatitis-oriented hospitals and clinics, based on antiviral therapeutic approaches.

In conclusion, the Elecsys HBsAg II assay correlated excellently with another commercially available HBsAg quantitative assay, and its mandatory onboard dilution algorithm added the additional advantage of the pre-dilution protocol, particularly useful under specific conditions such as the analysis of specimens from a hepatitis clinic or known hepatitis patients by reducing repeated measurements and increasing laboratory efficiency.

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Elecsys B형 간염 바이러스 표면항원 정량검사의 장비 내 희석 알고리즘에 의한 검사 효율성 향상

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배경: Elecsys HBsAg Ⅱ 정량검사는 비교적 최근에 도입된 분석법으로서, 분석 첫 단계부터 내장 1:400 희석을 적용하여 혈청 HBs 항원의 농도를 측정하는 알고리즘을 이용한다. Elecsys HBsAg Ⅱ 정량검사의 성능을 평가하고, 초기 내장 희석법이 검사실 효율성에 미치는 영향을 분석하였다.
방법: Elecsys 및 Architect HBsAg 정량검사로 HBs 항원의 양을 측정하였다. Elecsys HBsAg Ⅱ 정량검사의 직선성과 정밀도 및 Architect HBsAg 정량검사와의 상관성을 평가하였다. 정밀도는 대한민국 서울의 삼성서울병원, 세브란스병원, 서울성모병원에서 동일한 혈청 검체를 사용하여 검증하였다. 위 두 가지 정량검사법의 희석 알고리즘의 효율성은 1,848개의 임상 검체 결과를 이용하여 검증하였다.
결과: Elecsys HBsAg Ⅱ 정량검사는 0.1–48,000.0 IU/mL 농도 범위에서 예상치 및 측정치간 양호한 직선성을 나타내었다(r=0.9998). 세 개 기관에서 시행된 정밀도 평가에서 변이계수는 1.28–6.82%로 매우 우수하였다. Elecsys HBsAg Ⅱ 및 Architect HBs Ag 정량 수치는 상관성이 매우 우수하였으며 (n=506, r=0.987, P<0.001), 이는 HCV와 HBV 동시감염 환자의 혈청에서도 확인하였다(n=27). 효율성 평가에서, Elecsys HBsAg Ⅱ 정량검사의 내장 1:400 희석법을 이용하였을 때 전체 검체 중 64.0%는 추가 희석과정 없이 최종 HBs 항원 정량 수치를 보고할 수 있는 것으로 추산되었다.
결론: Elecsys HBsAg Ⅱ 정량검사는 정밀도가 매우 우수하고 기존 Architect 정량검사와의 상관성이 높음이 증명되었으며, 초기 HBs 항원의 농도가 높은 검체를 희석하여 재검할 필요성을 현저히 줄임으로써 검사실 효율성을 높이는 데 기여할 수 있음을 확인하였다.
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